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## NOTICE OF ALLOWANCE AND FEE(S) DUE

26138 7590 12/01/2009

Joseph R. Baker, APC Gavrilovich, Dodd & Lindsey LLP 4660 La Jolla Village Drive, Suite 750 San Diego, CA 92122 EXAMINER GUPTA, ANISH

PAPER NUMBER

ART UNIT

DATE MAILED: 12/01/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/575,537	08/29/2006	Richard Gallo 00	0015-019US1/SD2004-043-2	1656				
TITLE OF INVENTION: HUMAN CATHELICIDIN ANTIMICROBIAL PEPTIDES								

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	03/01/2010

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San Diego, CA 92	2122							(Depositor's name)
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APPLICATION NO.	FILING DATE			FIRST NAMED INVENTOR	₹	ATTO	RNEY DOCKET NO.	CONFIRMATION NO.
10/575,537	08/29/2006			Richard Gallo	00	015-0	19US1/SD2004-043-2	1656
TITLE OF INVENTION:	HUMAN CATHELICI		NTIMICROBIAL SUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSU	C DEEP	TOTAL FEE(S) DUE	DATE DUE
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4a. The following fee(s) an  Issue Fee Publication Fee (No	small entity discount p	ermitte		p. Payment of Fee(s): (Ple A check is enclosed. Payment by credit cs The Director is hereboverpayment, to Dep	rd. Form PTO-2038	is att	iched.	
5. Change in Entity Statu a. Applicant claims	SMALL ENTITY statu	s. See	37 CFR 1.27.	b. Applicant is no lo	nger claiming SMA	LLEN	ITTY status. Sec 37 CF	R 1.27(g)(2).
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10/575,537	77 08/29/2006 Richard Gallo		00	00015-019US1/SD2004-043-2 1656			
26138	7590	12/01/2009		EXAMINER			
Joseph R. Ba	Joseph R. Baker, APC			GUPTA, ANISH			
	Gavrilovich, Dodd & Lindsey LLP			ART UNIT	PAPER NUMBER		
4660 La Jolla Village Drive, Suite 750 San Diego, CA 92122				1654			

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 491 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 491 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

## Application No. Applicant(s) 10/575.537 GALLO ET AL. Notice of Allowability Examiner Art Unit ANISH GUPTA 1654 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to . 2. The allowed claim(s) is/are 1, 3-5, 7, 19, 21-23, 25, 28-29, 31-44, 50-54, 57-59 and 61. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) $\square$ All b) ☐ Some\* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). \* Certified copies not received: \_\_\_\_\_. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. | Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date Information Disclosure Statements (PTO/SB/08). 7. X Examiner's Amendment/Comment Paper No./Mail Date 4. T Examiner's Comment Regarding Requirement for Deposit 8. X Examiner's Statement of Reasons for Allowance of Biological Material 9. ☐ Other . /Anish Gupta/

Primary Examiner, Art Unit 1654

## EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or
additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312.
 To ensure consideration of such an amendment, it MUST be submitted no later than the payment of
the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Baker on November 23, 2009.

The application has been amended as follows:

Claims 9-18, 20, 24, 26, 27, 30, 45-49, 55-56, 60 and 62-68 are canceled.

The following claims have been amended:

- 1. A substantially purified polypeptide:
  - (a) consisting of 16-20 amino acids in length; and
- (b) containing the sequence X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>X<sub>4</sub>X<sub>3</sub>X<sub>6</sub>LKX<sub>7</sub>FX<sub>8</sub>X<sub>9</sub>X<sub>10</sub>LX<sub>11</sub>P (SEQ ID NO:1), wherein X<sub>1</sub>, X<sub>2</sub>, and X<sub>6</sub> are individually K or R; wherein X<sub>3</sub> is I or K; wherein X<sub>4</sub> is V or G; wherein X<sub>5</sub> is Q or R; wherein X<sub>5</sub>, X<sub>9</sub>, X<sub>10</sub>, and X<sub>11</sub> are each individually any amino acid; wherein X<sub>8</sub> is L or F and wherein the polypeptide comprises antibacterial and/or antimicrobial, antifungal, and/or antiviral activity.
- 4. A substantially purified polypeptide
  - (a) consisting of about 26 to [[30]] 28 amino acids in length; and
  - (b) containing the sequence  $X_1X_2X_3X_4X_5X_6IKX_7FX_6X_9X_{10}LX_{11}P$  (SEQ ID NO:1), wherein  $X_1$ ,  $X_2$ , and  $X_6$  are individually K or R; wherein  $X_3$  is I or K; wherein  $X_4$  is V or G; wherein  $X_5$  is Q or R; wherein  $X_5$ ,  $X_9$ ,  $X_{10}$ , and  $X_{11}$  are each individually any amino acid; wherein  $X_8$  is L or F and wherein the polypeptide comprises antibacterial and/or antimicrobial, antifungal, and/or antiviral activity.

- A substantially purified polypeptide consisting of a sequence selected from the group consisting of:
  - (a) RKSKEKIGKEFKRIVQRIKDFLRNLVP (SEQ ID NO:23);
  - (b) RKSKEKIGKEFKRIVQRIKDFLRNLVPR (SEQ ID NO:24);
  - (c) RKSKEKIGKEFKRIVQRIKDFLRNLVPRT (SEQ ID NO:25);
  - $\hbox{(d)} \qquad \hbox{RKSKEKIGKEFKRIVQRIKDFLRNLVPRTE (SEQ ID NO:26);}$
  - (e) RKSKEKIGKEFKRIVQRIKDFLRNLVPRTES (SEQ ID NO:27)
  - (f) LGDFFRKSKEKIGKEFKRIVORIKDFLRNLVPRTES (SEO ID NO:28).
- (b) containing the sequence  $X_1X_2X_3X_3X_2X_2IKX_2FX_3X_3X_{12}LX_{11}P$  (SEQ ID NO:1), wherein  $X_1$ ,  $X_2$ , and  $X_2$  are individually K or R; wherein  $X_2$  is I or I; wherein I is I or I; wherein I is I or I and wherein I is I or I and wherein the polypeptide comprises antibacterial and/or antifungal activity.
- 21. The method of claim [[20]] 19, wherein the peptide eomprises consists of a sequence selected from the group consisting of:
  - (a) [[NH<sub>2</sub>-]]KRIVQRIKDFLRNLVP[[-COOH]] (SEQ ID NO:13);
  - (b) [[NH<sub>2</sub>-]]KRIVQRIKDFLRNLVPR[[-COOH]] (SEQ ID NO:14);
  - (c)  $[[\mathrm{NH_2-}]] KRIVQRIKDFLRNLVPRT[[-COOH]] \ (SEQ \ ID \ NO:15);$
  - (d) [[NH<sub>2</sub>-]]KRIVQRIKDFLRNLVPRTE[[-COOH]] (SEQ ID NO:16); and

Application/Control Number: 10/575,537 Art Unit: 1654

- (e) [[NH<sub>2</sub>-]]KRIVQRIKDFLRNLVPRTES[[-COOH]] (SEQ ID NO:17).
- The method of elaim 19, wherein the A method of inhibiting the growth of a bacteria or fungus comprising contacting the bacteria or fungus with an inhibiting effective amount of a peptide
  - (a) consisting of about 26 to [[30]] 28 amino acids in length; and
  - (b) containing the sequence  $X_1X_2X_3X_4X_2X_4[KX_2FX_8X_2X_{10}LX_{11}P(SEQ ID NO:1)]$ , wherein  $X_1$ ,  $X_2$ , and  $X_4$  are individually K or R; wherein  $X_2$  is I or K; wherein  $X_2$  is V or G; wherein  $X_2$  is Q or R; wherein  $X_2$ ,  $X_2$ ,  $X_{10}$ , and  $X_{11}$  are each individually any amino acid; wherein  $X_2$  is L or E and wherein the polypeptide comprises antibacterial and/or antifungal activity.
- The method of claim 22, wherein the peptide comprises a sequence selected from the group consisting of:
  - [[NH,-][KSKEKIGKEFKRIVQRIKDFLRNLVP[[-COOH]] (SEQ ID NO:18);
  - (b) [[NH<sub>2</sub>-][KSKEKIGKEFKRIVQRIKDFLRNLVPR[[-COOH]] (SEQ ID NO:19);
  - (c) [[NH<sub>2</sub>-]]KSKEKIGKEFKRIVQRIKDFLRNLVPRT[[-COOH]] (SEQ ID NO:20);
    - (d)  $\hbox{[[NH_2-]]KSKEKIGKEFKRIVQRIKDFLRNLVPRTE[[-COOH]] (SEQ ID)}$

NO:21); and

(a)

- (e)  $[ [ \mathrm{NH_{2}-} ] ] \mathrm{KSKEKIGKEFKRIVQRIKDFLRNLVPRTES} [ -\mathrm{COOH} ] ] \mathrm{(SEQ\:ID\:NO:22)}.$
- 25. The method of claim 24, wherein the peptide comprises a <u>A method of inhibiting the growth of a bacteria or fungus comprising contacting the bacteria or fungus with an inhibiting effective amount of a polypeptide consisting of a sequence selected from the group consisting of:</u>
  - $\hbox{(a)} \qquad \hbox{[[NH$_2$-]]RKSKEKIGKEFKRIVQRIKDFLRNLVP[[-COOH]] (SEQ ID NO:23);}$
  - (b)  $[[\mathrm{NH_2-}]] \mathrm{RKSKEKIGKEFKRIVQRIKDFLRNLVPR} [[\mathrm{-COOH}]] \ (\mathrm{SEQ\ ID\ NO:24});$
- (c) [[NH $_2$ -]]RKSKEKIGKEFKRIVQRIKDFLRNLVPRT[[-COOH]] (SEQ ID

NO:25);

Art Unit: 1654

- (d)  $[\![\mathrm{NH_2}\!]\!] \mathsf{RKSKEKIGKEFKRIVQRIKDFLRNLVPRTE}[\![-\mathrm{COOH}]\!] \ (\mathsf{SEQ\ ID} \ \mathsf{NO:}26);$
- (e) [[NH<sub>2</sub>-]]RKSKEKIGKEFKRIVQRIKDFLRNLVPRTES[[-COOH]] (SEQ ID NO:27)
  - (f) LGDFFRKSKEKIGKEFKRIVORIKDFLRNLVPRTES (SEQ ID NO:28).
- 28. The method of claim 19, 22, or 25, wherein the contacting is in vitro.
- The method of claim 28, wherein the contacting is on a surface suspected of having a microbe bacteria or fungus.
- 31. The method of claim 19, 22 or 25, wherein the contacting is in vivo.
- 33. The method of claim [[30]] 19, 22 or 25, wherein the bacteria is gram positive.
- 35. The method of claim [[30]] 19, 22 or 25, wherein the bacteria is gram negative.
- 37. The method of claim 19, 22 or 25, wherein the peptide is administered in combination with at least one antibiotic.
- 39. The method of claim 37, wherein the antibiotic is selected from the group consisting of amikacin, gentamicin, kanamycin, netilmicin, t[[-]]obramycin, streptomycin, azithromycin, clarithromycin, erythromycin estolate/ethylsuccinate/gluceptatellactobionate/stearate, penicillin G, penicillin V, methicillin, nafcillin, oxacillin, cloxacillin, dicloxacillin, ampicillin, amoxicillin, ticarcillin, carbenicillin, mezlocillin, piperacillin, cephalothin, cefazolin, cefaclor, cefamandole, cefoxitin, cefuiroxime, cefonicid, cefinetazole, cefotetan, cefprozil, loracarbef, cefetamet, cefoperazone, cefotaxime, ceftizoxime, ceftraxone, ceftazidime, cefepime, cefixime, cefpodoxime, cefsulodin, i[[-]]mipenem, aztreonam, fleroxacin, nalidixic acid, norfloxacin,

Art Unit: 1654

ciprofloxacin, ofloxacin, enoxacin, lomefloxacin, cinoxacin, doxycycline, m[[-]]inocycline, tetracycline, vancomycin, and teicoplanin.

 A method of decontaminating a surface comprising contacting the surface with a composition comprising a cathelicidin functional fragment

(a) consisting of 16-20 amino acids in length; and

(b) containing the sequence  $X_1X_2X_1X_2X_2IKX_2FX_2X_2X_0LX_1P$  (SEQ ID NO:1), wherein  $X_1$ ,  $X_2$ , and  $X_2$  are individually K or R; wherein  $X_3$  is I or K; wherein  $X_2$  is V or V

- 57. The method of claim [[56]] 50, wherein the polypeptide comprises a sequence selected from the sequence consisting of:
  - (a) [[NH<sub>2</sub>-][KRIVQRIKDFLRNLVP[[-COOH]] (SEQ ID NO:13);
  - (b) [NH2-|KRIVQRIKDFLRNLVPR|J-COOH] (SEQ ID NO:14);
  - (c) [[NH<sub>2</sub>-]]KRIVQRIKDFLRNLVPRT[[-COOH]] (SEQ ID NO:15);
  - (d) [[NH<sub>2</sub>-][KRIVQRIKDFLRNLVPRTE][-COOH]] (SEQ ID NO:16); and
  - (e) [[NH<sub>2</sub>-]]KRIVQRIKDFLRNLVPRTES[[-COOH]] (SEQ ID NO:17).
- The Δ method of decontaminating a surface comprising contacting the surface with a composition comprising a cathelicidin functional fragment that claim 55, wherein the polypeptide
  - (a) is about 26 to [[30]] 28 amino acids in length; and
- (b) contains the sequence  $X_1X_2X_1X_1X_2X_1KX_2FX_2X_2X_{10}LX_{11}P$  (SEQ ID NO:1), wherein  $X_1$ ,  $X_2$ , and  $X_4$  are individually K or R; wherein  $X_3$  is 1 or K; wherein  $X_4$  is V or G; wherein  $X_5$  is Q or R; wherein  $X_2$ ,  $X_2$ ,  $X_{10}$ , and  $X_{11}$  are each individually any amino acid; wherein  $X_2$  is L or F and wherein the polypeptide comprises antibacterial and/or antifungal activity.
- 59. The method of claim 58, wherein the polypeptide comprises a sequence selected from the group consisting of:
  - (a) [[NH<sub>2</sub>-]]KSKEKIGKEFKRIVQRIKDFLRNLVP[[-COOH]] (SEQ ID NO:18);

Art Unit: 1654

- (b) [[NH<sub>2</sub>-]]KSKEKIGKEFKRIVQRIKDFLRNLVPR[[-COOH]] (SEQ ID NO:19);
- $\label{eq:cooh} \textbf{(c)} \qquad \textbf{[[NH$_2$-]]KSKEKIGKEFKRIVQRIKDFLRNLVPRT[[-COOH]] (SEQ ID NO:20);}$
- (d) [[NH<sub>2</sub>-]]KSKEKIGKEFKRIVQRIKDFLRNLVPRTE[[-COOH]] (SEQ ID
- NO:21); and
- (e) [[NH<sub>2</sub>-]]KSKEKIGKEFKRIVQRIKDFLRNLVPRTES[[-COOH]] (SEQ ID NO:22).
- 61. The method of claim 60, wherein the polypeptide comprises Δ method of decontaminating a surface comprising contacting the surface with a composition comprising a cathelicidin functional fragment consists of a sequence selected from the group consisting of:
  - (a) [[NH<sub>2</sub>-][RKSKEKIGKEFKRIVQRIKDFLRNLVP][-COOH]] (SEQ ID NO:23);
  - (b)  $[[\mathrm{NH}_2\text{-}]] RKSKEKIGKEFKRIVQRIKDFLRNLVPR[[-COOH]] (SEQ ID NO:24);$
  - (c) [[NH<sub>2</sub>-]]RKSKEKIGKEFKRIVQRIKDFLRNLVPRT[[-COOH]] (SEQ ID
- NO:25);
- (d)  $[NH_2-]$ RKSKEKIGKEFKRIVQRIKDFLRNLVPRTE[[-COOH]] (SEQ ID NO:26);
- (e) [[NHz-]]RKSKEKIGKEFKRIVQRIKDFLRNLVPRTES[[-COOH]] (SEQ ID NO:27)
  - (f) LGDFFRKSKEKIGKEFKRIVQRIKDFLRNLVPRTES (SEQ ID NO:28).

### Examiner's Comments

 Support for the amendment to claims 4, 22, and 58 can be found on the paragraph bridging page 11-12, page 12, paragraph [0050] and page 13, paragraph [0054].

### Reasons For Allowance

3. The following is an examiner's statement of reasons for allowance:

The claims are drawn to peptides between 16-20 amino acids and 26-28 amino acids in length and having the sequence  $X_1X_2X_3X_4X_5X_6IKX_7FX_8X_9X_{10}LX_{11}P$  (SEQ ID NO:1), wherein  $X_1$ ,  $X_2$ , and  $X_6$  are individually K or R; wherein  $X_3$  is I or K; wherein  $X_4$  is V or G; wherein  $X_5$  is Q or R; wherein  $X_5$ ,  $X_{50}$ , and  $X_{11}$  are each individually any amino acid; wherein  $X_8$  is L or F and wherein the polypeptide comprises antibacterial and/or, antifungal, activity.

The prior art of Johansson et al. (J. of Biol. Chem.) teaches two peptides that are the

truncated versions of LL-37. The peptides have the sequence
FFRKSKEKIGKEFKRIVQRIKDFLRNLVPRTES (FF33) and
SKEKIGKEFKRIVQRIKDFLRNLVPRTES (SK29) (see page 3719). The reference discloses that
both of these peptides had lower antibacterial activity relative to the native LL-37
(LLGDFFRKSKEKIGKEFKRIVQRIKDFLRNLVPRTES) 9see page 3723). The shorter of the
two, SK29 had less activity than the FF-33 peptide in medium E against D21 (see page 3722 and

figure C). The claimed peptides are shorter than the peptides taught in Johansson et al.

The claims of the instant application are novel and unobvious because Johansson does not teach nor suggest that the peptides shorter than 29 amino acids. The reference also does not provide any motivation to make peptides shorter than 29 amino acids. The reference teaches that the truncated peptides lost antibacterial, with the shortest peptide having the worst activity against D21 in medium E. Accordingly, one would also expect losses in antibacterial activity of even shorter peptides of lengths between 16-20 and 26-28 amino acids as claimed. Thus, one would not be motivated to make shorter peptides given the teachings of Johansson et al.

Application/Control Number: 10/575,537 Art Unit: 1654 Page 9

Any comments considered necessary by applicant must be submitted no later than the

payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee.

Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

1. Any inquiry concerning this communication or earlier communications from the examiner

should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach

the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally

be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/

Primary Examiner, Art Unit 1654